



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

December 31, 2015

Lisa Adamson
Control Solutions, Inc.
5903 Red Genoa Bluff
Pasadena, TX 77507

Subject: Label Amendment – Revising application instructions
Product Name: Flee Multi-Dose for Dogs
EPA Registration Number: 53883-360
Application Date: August 19, 2015
Decision Number: 508459

Dear Ms. Adamson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Control Solutions, Inc. Master Label

08.19.2015 Fast Track Amend to revise application instructions

Information in [] is optional.

EPA No. 53883-360

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.] Information in italics is included for the reviewer only.

Flee Multi-Dose for Dogs

(“Dogs” must be 75% the height of the largest letter in the brand name)

FOR USE ONLY BY LICENSED VETERINARIANS ON DOGS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

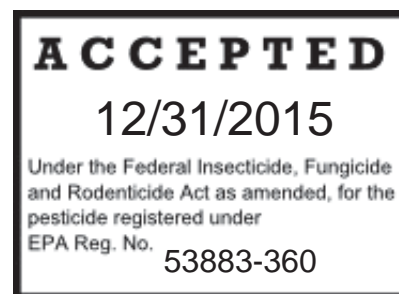
For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. Keep product in its original container. Do not repackage. Do not use bottle and applicator with any other product.

One of the following statements will appear on the front panel.

Use ONLY on dogs [&] [and] puppies 5 to 132 lbs., over 8 weeks old OR
ONLY For Dogs & Puppies, older than 8 weeks [&] [and] 5 to 132 lbs.

[insert large clear picture of dog in the weight range – on front panel]

[1.5 x 1.5 cm on front panel – lower right hand corner]



ACTIVE INGREDIENT:

Fipronil..... 9.70%

OTHER INGREDIENTS:..... 90.30%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See [Back][Label] for Additional Precautionary Statements]

Net Contents: [0.68 fl oz (20.11 ml)]

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FIRST AID	
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or a doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin:	<ul style="list-style-type: none">• Wash with plenty of soap and water.• Get medical attention if irritation persists.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also want to contact SafetyCall at 1-866-897-8050 for emergency medical treatment information.	

READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.

[[**Brand Name**] for dogs delivers [effective] protection against fleas, ticks, [and chewing lice]. [This product aids in the control of sarcoptic mange mites.] [**Brand Name** kills] [Kills] deer ticks, brown dog ticks, American dog ticks, and lone star ticks, including those transmitting Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases. Stops existing flea infestation and reinfestation for [[4] [four] weeks] [[1] [one] month] [30 days].]

Apply as a [spot] [stripe] to your dog to kill fleas, ticks [mosquitoes] and chewing lice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

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HAZARDS TO DOMESTIC ANIMALS.

For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat a dog with more than one pesticide product at a time. Over dosing a dog can result in serious illness and even death. As with any product, use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND THE DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on rabbits or animals other than dogs. Do not allow the dog to ingest this product. Do not use on puppies under 8 weeks of age. Weigh dog to be sure you are applying the right dose formulated for the weight of the dog. Do not apply more than once every [4 weeks] [30 days]. Do not double-dose dogs larger than 132 lbs. Instruct the dog owner to separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

(This statement will be placed on the back panel at the lower right corner of the market label)

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, advise dog owner to consult with veterinarian or SafetyCall at 1-866-897-8050.

[1.5 x 1.5 cm on back panel at the lower right corner]



[Back Panel]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

For use only by licensed veterinarians on dogs in their control or under their immediate supervision

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How to Apply

Accurately weigh the dog or puppy. Use the dog or puppy weight to determine the correct application rate, using the following chart.

Application Rate*		
Only for dogs weighing	Apply	Number of Applicator Tip Pumps/Squeezes
5 [-][to] 22 lbs.	0.67 ml	1
23 [-][to] 44 lbs.	1.34 ml	2
45 [-][to] 88 lbs.	2.68 ml	4
89 [-][to] 132 lbs.	4.02 ml	6

*Do not apply to dogs weighing less than 5 lbs. or less than 8 weeks of age. Do not double-dose dogs larger than 132 lbs.

APPLICATOR TIP PICTURE



Dog/Puppy (over 8 weeks old) Application Steps:

1. Twist the applicator cap to break the seal and remove. [This seal is broken only upon first use.] retain cap as it is used to re-seal the applicator after applying product dose[s].
2. Holding neck of device vertically, twist the applicator nozzle, as unlock arrows indicate, you will hear a click.
3. Invert the bottle with the device over the dog's back.

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4. Part the dog's hair, so that the product can be applied directly to the skin.
5. Apply as a spot to the [back] [base] of the dog's neck, above the shoulder blades [start at the shoulder and apply towards the tail].
6. First Application: Pump the applicator once [all the way until it stops expelling the product][all the way down to get the full dose].
7. Multiple Applications: Repeat steps 3 - 6 for each pump (see table above for number of pumps). Do not apply more product than what is listed for your dog's weight.
8. Replace the cap on the applicator and lock the device by following the lock arrows [by twisting the top of the applicator after application].
9. Keep out of reach of children.

Do not apply more frequently than once every 4 weeks.

FREQUENCY OF APPLICATION

[Brand Name] [This product] should be applied once every [30 days] [4 weeks] [month].

Treatment remains effective, even after bathing, water immersion, or exposure to sunlight. Do not reapply [Brand Name] for 30 days [4 weeks] [1 month]

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STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep product in its original container. Do not repack. Store in a cool (below 77°F [7][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

APPLICATOR DISPOSAL: Do not reuse the applicator once the bottle is empty. Discard disposable applicator in accordance with State and Local regulations.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Optional recycling graphic]

LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as presence of other materials, or the manner of use or application, all of which are beyond the control of Control Solutions, Inc. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Control Solutions, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Control Solutions, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Control Solutions, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Control Solutions, Inc. election, the replacement of product.

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[If you have questions or comments about this product, please write: CSI Consumer Response, 5903 Genoa-Red Bluff Road, Pasadena, TX 77507]

[In Case of Emergency, call: XXX-XXX-XXXX]

[Non-Emergency, call XXX-XXX-XXXX]
[Formulated in the USA]

Control Solutions, Inc.
5903 Genoa-Red Bluff Road
Pasadena, TX 77507

EPA Reg. No. 53883-360
EPA Est. No. XXXX-XXX-XXX

[BAR CODE AREA][Lot code]

[START – METERED DOSING APPLICATOR/BOTTLE LABEL]

{Front Label}	{Back Label}
Flee Multi-Dose for Dogs Fipronil 9.7% 0.68 fl oz [(20.10 ml)] EPA REG. No. 53883-360 Use ONLY on dogs [&] [and] puppies 5 to 132 lbs., over 8 weeks old OR ONLY For Dogs & Puppies, older than 8 weeks [&] [and] 5 to 132 lbs.	KEEP OUT OF REACH OF CHILDREN CAUTION: Read all directions and precautions on the label before using.

[END – METERED DOSING APPLICATOR/BOTTLE LABEL]

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Optional marketing claims

[Use in animal shelters, under direct supervision of a veterinarian]
[Multi-dose dispenser with metering applicator]
[Convenient multi-dose dispenser with metering applicator for in clinic use]
[Convenient multi-dose dispenser for animal facility use]
[Accurate dosing for use on all sizes of dogs]
[Convenient dosing for use on all sizes of dogs]
[Weigh dog to determine appropriate dose]
[For use only by licensed veterinarians] [and use on animals under control or immediate supervision of a licensed veterinarian]]
[Weigh dog and determine appropriate application rate using chart]

[Bottle and Applicator is specifically calibrated for this Product only.]
[Applicator is calibrated to accurately apply the specified rate for dogs]
[Refer to Application Rate Table to determine the number of pumps][squeezes][pump/squeezes]]
[Refer to Application Rate Table to determine the number of [pumps][squeezes][pump/squeezes] for each weight category]
[Product comes with cap and applicator.]
[Applicator pump works only when applicator tip is pointing down]
[Do not [activate pump][squeeze pump] while applicator tip is pointing up]
[Applicator will not deliver a full dose if applicator tip is pointing up while [squeezing pump][applying][activating pump]]
[Please refer to full label for additional information.]
[As with any product, use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction.]

[Chewing Lice Claims]

[Kills] [chewing lice] [lice] [rapidly] [infestations]

[Mite Claims]

[Controls] [Aids in the control] [of] [sarcoptic mange infestations]

[Flea Claims]

[Kill Fleas]

[Kills [adult] fleas [for] [up to] [4 weeks] [90 days] [three months] [3 months] [1 month]]
[Kills newly emerged adult fleas before they lay eggs]
[Kills [adult] [fleas] [causing] [responsible for] [flea allergy dermatitis] [and] [flea bite anemia]]
[Puts a stop to existing [flea] infestations] [and] [prevents new infestations]]
[Monthly application may be needed for dogs with high risk for flea reinfestation]

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[Tick Claims]

[Kills ticks] [,] [including those transmitting Lyme disease]

[Kills [all stages of] ticks [up to [4 weeks] [1 month] [30 days]]

[Kills [brown dog ticks] [(*Rhipicephalus sanguineus*)] [,] [American dog ticks] [(*Dermacentor variabilis*)] [,] [lone star ticks] [,] [and] [deer ticks] [including ticks that may cause] Lyme disease] [,Rocky Mountain spotted fever] [,ehrlichiosis] [,babesiosis] [,anaplasmosis] [and] [other tick-borne diseases]]

[Multiple Pest Claims]

[Kills chewing lice [,] [ticks] [and] [aids in control of sarcoptic mange mites]]

[Tick [and] flea control for dogs [,including puppies over 8 weeks]]

[Kills fleas, [&] [and] ticks, [&] [and] [chewing] [lice] [monthly]]

[Once a monthly flea, tick, mosquito and chewing lice [application] [treatment] [protection]]

[Effectively kills ticks, [fleas] and chewing lice [,including control of sarcoptic mange mites]]

[[4 Week] [1 month] [30 day] [Flea and Tick Treatment]]

[[Four (4) Week] [1 Month] [Flea, Tick, and Chewing [Lice Control] [Treatment] [Application]]

[Use [**Brand Name**] monthly to kill ticks and chewing lice]

[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]

[Other Pest Claims]

[Use on Dogs and Puppies 8 weeks of age or older]

[Apply] [to] puppies over 8 weeks of age]

[Specially Formulated for Dogs and Puppies 8 weeks of age or older]

[For Dogs [weighing 5 to 132 lbs.]]

[Convenient applicator]

[Convenient spot-on product]

[Easy to Use]

[Apply monthly]

[Apply once every [4 weeks] [month] [30 days]!]





[Waterproof]

[Fast-acting]

[Long-lasting]

[Effective after bathing [and] [exposure to water and sunlight]]

[Optional graphics below may or may not appear anywhere on finished label]

	Adult Flea	
	Fleas	

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	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Lone Star Tick	
	Chewing Lice	
	Mite	